FDA's Office of Drug Evaluation III Denies Agile Therapeutics, Inc.'s Initial Formal Dispute Resolution Request

July 24, 2018

Company Plans to Appeal to the FDA's Office of New Drugs

PRINCETON, N.J., July 24, 2018 (GLOBE NEWSWIRE) -- Agile Therapeutics, Inc., (Nasdaq:AGRX) (the "Company"), a women's healthcare company, today announced that the Office Director of the FDA's Office of Drug Evaluation III (ODEIII) has affirmed the position of the Division of Bone, Reproductive and Urologic Products (DBRUP) and denied the Company's appeal of the December 21, 2017 Complete Response Letter in relation to the New Drug Application (NDA) for Twirla®. The Company had appealed the decision by DBRUP that concerns surrounding the *in vivo* adhesion properties of Twirla prevent its approval and cannot be addressed through the Company's proposed patient compliance programs. The Company intends to appeal the ODEIII decision to the Office of New Drugs.

Agile initiated formal dispute resolution with the FDA's ODEIII on June 6, 2018 to appeal the December 21, 2017 CRL for Twirla. The appeal was submitted in accordance with the formal dispute resolution process following an end-of-review meeting in April 2018 in which the FDA provided the Company with a more complete understanding of its assessment of the Twirla NDA and the adhesion data for Twirla contained therein. The formal dispute resolution process exists to encourage open, prompt discussion of scientific and procedural disputes that arise during drug development, new drug review, and post-marketing oversight processes of the FDA. Through this process the Company has the ability to escalate its appeal to additional levels of FDA management.

"We are clearly disappointed in the Office Director's decision to deny our formal dispute resolution request," said Al Altomari, Chairman and Chief Executive Officer, Agile Therapeutics. "We disagree with the Office Director's conclusions and continue to believe that our Phase 3 SECURE trial yielded *in vivo* adhesion data that are adequate for Twirla's approval, and more importantly, that did not impact clinical outcomes. We look forward to discussing our positions with a representative from the Office of New Drugs as we continue to pursue formal dispute resolution."

About Twirla® (AG200-15)
Twirla (levonorgestrel/ethinyl estradiol transdermal system) or AG200-15 is an investigational low-dose, once-weekly contraceptive patch. AG200-15 is a combined hormonal contraceptive (CHC) patch that contains the active ingredients ethinyl estradiol (EE), a type of estrogen and levonorgestrel (LNG), a type of progestin. Twirla is designed to be applied once weekly for three weeks, followed by a week without a patch. Agile received a complete response letter (CRL) from the FDA on December 21, 2017 relating to the New Drug Application (NDA) for Twirla. In the CRL, the FDA informed the Company that the product could not be approved in its present form due to deficiencies related to quality adhesion test methods, observations identified during the pre-approval inspection of the manufacturing facility for Twirla, and because of questions the FDA had on the *in vivo* adhesion properties of Twirla and their potential relationship to the Company's Phase 3 clinical trial results. As announced on May 18, 2018, Agile met with the FDA during a Type A meeting on April 16, 2018 to discuss the CRL and received the official end of review (EOR) minutes on May 15, 2018. The Company initiated formal dispute resolution with the FDA on June 6, 2018 in response to the FDA's position on Twirla's *in vivo* adhesion properties communicated in the EOR minutes. The Company believes the FDA provided guidance on a path forward for addressing the manufacturing issues related to Twirla.

About Agile Therapeutics, Inc.
Agile Therapeutics is a forward-thinking women's healthcare company dedicated to fulfilling the unmet health needs of today's women. Our product candidates are designed to provide women with contraceptive options that offer freedom from taking a daily pill, without committing to a longer-acting method. Our lead product candidate, Twirla® (levonorgestrel/ethinyl estradiol transdermal system) or AG200-15, is an investigational low-dose, non-daily, prescription contraceptive. Twirla is based on our proprietary transdermal patch technology, called Skinfusion®, which is designed to allow drug delivery through the skin. For more information, please visit the company website at www.agiletherapeutics.com. The Company may occasionally disseminate material, nonpublic information on the Company's website.

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Forward-Looking Statement
Certain information contained in this press release includes "forward-looking statements" related to our regulatory submissions and projected cash position. We may, in some cases use terms such as "predicts," "believes," "potential," "continue," "anticipates," "estimates," "expects," "plans," "intends," "may," "could," "might," "likely," "will," "should" or other words that convey uncertainty of the future events or outcomes to identify these forward-looking statements. Our forward-looking statements are based on current beliefs and expectations of our management team that involve risks, potential changes in circumstances, assumptions, and uncertainties, including statements regarding our ability to succeed in formal dispute resolution with the FDA, which can be lengthy and expensive and the success of which is not guaranteed and our belief that Twirla's adhesion profile is adequate for approval and a reformulation of Twirla is not necessary. Any or all of the forward-looking statements may turn out to be wrong or be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties. These forward looking statements are subject to risks and uncertainties including risks related to our ability to either succeed in our formal dispute resolution with the FDA, or, if we are unsuccessful, our ability to develop a reformulation that will address the FDA's concerns, if we are required to reformulate Twirla, our ability to successfully complete an additional adhesion study and bioequivalence study, the potential that we may be required to conduct an additional Phase 3 trial, the likelihood that we will require additional correspondence with the FDA prior to the resubmission of our NDA, our ability to resubmit and the timing of our resubmission of the NDA for Twirla, FDA acceptance and approval of the resubmitted NDA, or whether other issues will arise that will negatively impact acceptance, review, and approval of Twirla by the FDA, our ability to address the deficiencies identified by the FDA in the CRL issued in December 2017 and in the Type A meeting minutes issued in May 2018, and unforeseen market factors or events in our clinical and manufacturing development plans and the other risks set forth our filings with the U.S. Securities and Exchange Commission, including our Annual Report on Form 10-K and our Quarterly

Reports on Form 10-Q. For all these reasons, actual results and developments could be materially different from those expressed in or implied by our forward-looking statements. You are cautioned not to place undue reliance on these forward-looking statements, which are made only as of the date of this press release. We undertake no obligation to publicly update such forward-looking statements to reflect subsequent events or circumstances.

SOURCE: Agile Therapeutics, Inc.

Contact:
Investor Relations
Agile Therapeutics
609-683-1880


Primary Logo

Source: Agile Therapeutics, Inc.